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ATTORNEYS FOR PLAINTIFFS PAR PHARMACEUTICAL, INC.,

PAR STERILE PRODUCTS, LLC, AND

ENDO PAR INNOVATION COMPANY, LLC

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

PAR PHARMACEUTICAL, INC., PAR
STERILE PRODUCTS, LLC, and ENDO PAR
INNOVATION COMPANY, LLC

Plaintiffs,

v.

SANDOZ INC.

Defendant.

Civil Action No. 3:18-cv-14895-BRM-
DEA

PLAINTIFF'S ANSWER TO DEFENDANT'S COUNTERCLAIMS

Plaintiffs Par Pharmaceutical, Inc., Par Sterile Products, LLC, and Endo Par Innovation Company, LLC (collectively "Par"), hereby set forth their Answer to the Counterclaims of Defendant Sandoz Inc. ("Sandoz") as follows:

NATURE OF THE ACTION

1. Paragraph 1 states legal conclusions to which no answer is required. To the extent an answer is required, Par admits that Sandoz seeks declaratory judgments that U.S. Patent Nos. 9,375,478 ("the '478 Patent"), 9,687,526 ("the '526 Patent"), 9,744,209 ("the '209 Patent"), 9,744,239 ("the '239 Patent"), 9,750,785 ("the '785 Patent"), and 9,937,223 ("the '223 Patent") (collectively, "the Patents-in-Suit") are invalid and are not infringed by Sandoz's

submission of ANDA Nos. 212068 and 212069 (the “Sandoz ANDAs”) and will not be infringed by the commercial manufacture, importation, sale, or offer for sale of Sandoz’s Proposed ANDA Products upon FDA approval. Par does not contest that this Court has subject matter jurisdiction over Sandoz’s Counterclaims. Except as expressly admitted, Par denies the remaining allegations of Paragraph 1 as stated.

THE PARTIES

2. Par admits the allegations of Paragraph 2 upon information and belief.
3. Par admits the allegations of Paragraph 3.
4. Par admits the allegations of Paragraph 4.
5. Par admits the allegations of Paragraph 5.
6. Par admits the allegations of Paragraph 6.
7. Par admits the allegations of Paragraph 7.
8. Par admits the allegations of Paragraph 8.
9. Par admits the allegations of Paragraph 9.
10. Par admits the allegations of Paragraph 10.
11. Par admits the allegations of Paragraph 11.

JURISDICTION & VENUE

12. Paragraph 12 states legal conclusions to which no answer is required. To the extent an answer is required, Par denies that Sandoz states or has any valid counterclaims.

13. Paragraph 13 states legal conclusions to which no answer is required. To the extent an answer is required, Par does not contest that this Court has subject matter jurisdiction over these Counterclaims.

14. Paragraph 14 states legal conclusions to which no answer is required. To the extent an answer is required, Par does not contest personal jurisdiction in this judicial district for the limited purpose of this action only. Par denies the remaining allegations of Paragraph 14.

15. Paragraph 15 states legal conclusions to which no answer is required. To the extent an answer is required, Par does not contest that venue in this judicial district with respect to Sandoz's Counterclaims is proper.

BACKGROUND

16. Par admits that on October 11, 2018, it filed a Complaint in this Court. The Complaint speaks for itself.

17. Par admits that on November 8, 2018, it filed a Complaint in this Court. The First Amended Complaint speaks for itself.

18. Paragraph 18 states legal conclusions to which no answer is required. To the extent an answer is required, Par does not dispute that a judicable controversy exists between the parties regarding infringement of the Patents-in-Suit. Except as expressly admitted, Par denies the remaining allegations of Paragraph 24.

19. Par admits the allegations of Paragraph 19.

20. Paragraph 20 states legal conclusions to which no answer is required. To the extent an answer is required, Par does not dispute that it submitted NDA No. 204485 to the U.S. Food and Drug Administration ("FDA") pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act.

21. Paragraph 21 states legal conclusions to which no answer is required. To the extent an answer is required, and to the extent Par understands the allegations of this paragraph, Par denies the allegations of this paragraph.

22. Paragraph 22 states legal conclusions to which no answer is required. To the extent an answer is required, Par admits that it relied, at least in part, on published literature in connection with its 505(b)(2) NDA submissions, and that this paragraph accurately quotes the FDA's March 27, 2014 Summary Review. Par denies the remaining allegations of Paragraph 22.

23. Paragraph 23 states legal conclusions to which no answer is required. To the extent an answer is required, and to the extent Par understands the allegations of this paragraph, Par denies the allegations of Paragraph 23.

24. Par lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 24, as the term Pitressin is not defined or otherwise specified, and thus Par denies those allegations as stated.

25. Par lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 25, as the term "Pitressin product" is not defined or otherwise specified, and thus Par denies those allegations as stated.

26. Par admits the source and language of the quotation included in Paragraph 26 is accurately represented. All remaining allegations of Paragraph 26 are denied.

27. Paragraph 27 contains legal conclusions to which no answer is required. To the extent an answer is required, Par admits that in June 2006, FDA issued guidance entitled "Marketed Unapproved Drugs—Compliance Policy Guide," that has since been revised. Par denies the remaining allegations as stated.

28. Paragraph 28 contains legal conclusions to which no answer is required. To the extent an answer is required, the June 2006 Guidance speaks for itself.

29. Paragraph 29 contains legal conclusions to which no answer is required. To the extent an answer is required, the June 2006 Guidance speaks for itself.

30. Paragraph 30 contains legal conclusions to which no answer is required. To the extent an answer is required, the June 2006 Guidance speaks for itself.

31. Paragraph 31 contains legal conclusions to which no answer is required. To the extent an answer is required, the June 2006 Guidance speaks for itself.

32. Par admits the allegations of Paragraph 32.

33. Paragraph 33 contains legal conclusions to which no answer is required. To the extent an answer is required, the June 2006 and September 2011 Guidances speak for themselves.

34. Par lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 34, including because the allegations of this paragraph are unduly vague and ambiguous, and thus denies them.

35. Par admits the allegations of Paragraph 35.

36. Par admits the allegations of Paragraph 36.

37. Par denies the allegations of Paragraph 37.

38. Par admits that on December 17, 2016, the FDA issued an approval letter for Par's Supplemental New Drug Application dated March 18, 2016, which approved an application for vasopressin injection, USP, 200 units per 10 mL. Except as expressly admitted, Par denies the remaining allegations of Paragraph 38.

39. Par admits that it sells in the United States and this district drug products using the tradename Vasostriect® approved for sale under NDA No. 204485. Except as expressly admitted, Par denies the remaining allegations of Paragraph 39 as stated.

40. Par admits the allegations in Paragraph 40, upon information and belief.

41. Par admits upon information and belief that there are products containing vasopressin that were sold commercially in the United States prior to April 17, 2014 that are no longer on sale in the United States. Except as expressly admitted, Par denies the remaining allegations of Paragraph 41 as stated.

42. Par lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 42 as stated, and thus denies them.

43. Par admits that the earliest filing date for any of the patent applications that issued as one of the Patents-in-Suit, as distinct from the earliest effective filing date to which any such applications may be entitled to claim the benefit of, is May 20, 2015.

44. Par admits the allegations of Paragraph 44.

45. Par admits the allegations of Paragraph 45.

46. Paragraph 46 states legal conclusions to which no answer is required. To the extent an answer is required, Par denies the allegations of Paragraph 46 as stated.

47. Paragraph 47 states legal conclusions to which no answer is required. To the extent an answer is required, Par denies the allegations of Paragraph 47 as stated.

48. Par admits the allegations of Paragraph 48, upon information and belief.

49. Par admits that, in a letter dated August 31, 2018, Sandoz gave written notification to Par of Sandoz's submission of ANDA No. 212069 containing Paragraph IV certifications alleging that the Patents-in-Suit are invalid and/or will not be infringed by Sandoz's Proposed ANDA Products. Except as expressly admitted, Par denies the remaining allegations of Paragraph 49 as stated.

50. Par admits that, in a letter dated August 31, 2018, Sandoz provided an Offer for Confidential Access to ANDA No. 212069 to Par. Except as expressly admitted, Par denies the remaining allegations of Paragraph 50 as stated.

51. Paragraph 51 states legal conclusions to which no answer is required. To the extent an answer is required, Par admits that Sandoz provided a notice letter dated August 31, 2018 as described in Paragraph 50 above. Par denies the remaining allegations of Paragraph 51.

52. Paragraph 52 states legal conclusions to which no answer is required. To the extent an answer is required, Par denies the remaining allegations of Paragraph 52 as stated.

53. Par admits that it commenced this action on October 11, 2018, and that it asserts claims against Sandoz for infringement of the Patents-in-Suit under 35 U.S.C. § 271(e)(2). Except as expressly admitted, Par denies the remaining allegations of Paragraph 53 as stated.

54. Par admits that it did not accept Sandoz's offer of confidential access to its ANDA, and that such access was not required for Par to determine that it was entitled to assert claims against Sandoz for infringement of the Patents-in-Suit. Except as expressly admitted, Par denies the remaining allegations of Paragraph 54 as stated.

55. Par admits that, in a letter dated October 17, 2018, Sandoz gave written notification to Par of Sandoz's submission of the Sandoz ANDA and that the written notification states that that ANDA No. 212068 contained Paragraph IV certifications asserting that the '478, '526, '209, '239, and '785 Patents are invalid and/or will not be infringed by the Sandoz Proposed ANDA Products. Except as expressly admitted, Par denies the remaining allegations of Paragraph 55 as stated.

56. Par admits that, in a letter dated October 17, 2018, Sandoz provided an Offer for Confidential Access to ANDA No. 212068 to Par. Except as expressly admitted, Par denies the remaining allegations of Paragraph 56 as stated.

57. Paragraph 57 states legal conclusions to which no answer is required. To the extent an answer is required, Par admits that Sandoz provided a notice letter dated October 17, 2018 as described in Paragraph 55 above. Par denies the remaining allegations of Paragraph 57.

58. Paragraph 58 states legal conclusions to which no answer is required. To the extent an answer is required, Par denies the allegations of this paragraph as stated.

59. Par admits the allegations of Paragraph 59.

60. Par admits that it did not accept Sandoz's offer of confidential access to its ANDA, and that such access was not required for Par to determine that it was entitled to assert claims against Sandoz for infringement of the Patents-in-Suit. Except as expressly admitted, Par denies the remaining allegations of Paragraph 60 as stated.

61. Paragraph 61 states legal conclusions to which no answer is required. To the extent an answer is required, Par does not dispute a justiciable controversy exists between the parties regarding the validity and infringement of the '478 Patent. Except as expressly admitted, Par denies the remaining allegations of Paragraph 61.

62. Paragraph 62 states legal conclusions to which no answer is required. To the extent an answer is required, Par does not dispute a justiciable controversy exists between the parties regarding the validity and infringement of the '526 Patent. Except as expressly admitted, Par denies the remaining allegations of Paragraph 62.

63. Paragraph 63 states legal conclusions to which no answer is required. To the extent an answer is required, Par does not dispute a justiciable controversy exists between the

parties regarding the validity and infringement of the '209 Patent. Except as expressly admitted, Par denies the remaining allegations of Paragraph 63.

64. Paragraph 64 states legal conclusions to which no answer is required. To the extent an answer is required, Par does not dispute a justiciable controversy exists between the parties regarding the validity and infringement of the '239 Patent. Except as expressly admitted, Par denies the remaining allegations of Paragraph 64.

65. Paragraph 65 states legal conclusions to which no answer is required. To the extent an answer is required, Par does not dispute a justiciable controversy exists between the parties regarding the validity and infringement of the '785 Patent. Except as expressly admitted, Par denies the remaining allegations of Paragraph 65.

66. Paragraph 66 states legal conclusions to which no answer is required. To the extent an answer is required, Par does not dispute a justiciable controversy exists between the parties regarding the validity and infringement of the '223 Patent. Except as expressly admitted, Par denies the remaining allegations of Paragraph 66.

FIRST COUNTERCLAIM
Noninfringement of the '478 Patent

67. Par incorporates by reference its responses to each of the preceding paragraphs of Sandoz's Counterclaims.

68. Paragraph 68 states legal conclusions to which no answer is required. To the extent an answer is required, Par does not dispute that a justiciable controversy exists between the parties regarding infringement of the '478 Patent. Except as expressly admitted, Par denies the remaining allegations of Paragraph 68.

69. Paragraph 69 states legal conclusions to which no answer is required. To the extent an answer is required, Par does not dispute that Sandoz seeks a declaration that the '478 Patent is not infringed by the Sandoz Proposed ANDA Products.

70. Par denies the allegations in Paragraph 70.

71. Par denies the allegations of Paragraph 71.

72. Par denies the allegations of Paragraph 72.

SECOND COUNTERCLAIM
Invalidity of the '478 Patent

73. Par incorporates by reference its responses to each of the preceding paragraphs of Sandoz's Counterclaims.

74. Paragraph 74 states legal conclusions to which no answer is required. To the extent an answer is required, Par does not dispute that a justiciable controversy exists between the parties regarding the validity of the '478 Patent. Except as expressly admitted, Par denies the remaining allegations of Paragraph 74.

75. Par denies the allegations in Paragraph 75.

76. Par denies the allegations of Paragraph 76.

77. Par denies the allegations of Paragraph 77.

78. Par denies the allegations of Paragraph 78.

79. Par denies the allegations of Paragraph 79.

THIRD COUNTERCLAIM
Noninfringement of the '526 Patent

80. Par incorporates by reference its responses to each of the preceding paragraphs of Sandoz's Counterclaims.

81. Paragraph 81 states legal conclusions to which no answer is required. To the extent an answer is required, Par does not dispute that a justiciable controversy exists between

the parties regarding infringement of the '526 Patent. Except as expressly admitted, Par denies the remaining allegations of Paragraph 81.

82. Paragraph 82 states legal conclusions to which no answer is required. To the extent an answer is required, Par does not dispute that Sandoz seeks a declaration that the '526 Patent is not infringed by the Sandoz Proposed ANDA Products.

83. Par denies the allegations in Paragraph 83.

84. Par denies the allegations of Paragraph 84.

85. Par denies the allegations of Paragraph 85.

FOURTH COUNTERCLAIM
Invalidity of the '526 Patent

86. Par incorporates by reference its responses to each of the preceding paragraphs of Sandoz's Counterclaims.

87. Paragraph 87 states legal conclusions to which no answer is required. To the extent an answer is required, Par does not dispute that a justiciable controversy exists between the parties regarding the validity of the '526 Patent. Except as expressly admitted, Par denies the remaining allegations of Paragraph 87.

88. Par denies the allegations in Paragraph 88.

89. Par denies the allegations of Paragraph 89.

90. Par denies the allegations of Paragraph 90.

91. Par denies the allegations of Paragraph 91.

92. Par denies the allegations of Paragraph 92.

FIFTH COUNTERCLAIM
Noninfringement of the ‘209 Patent

93. Par incorporates by reference its responses to each of the preceding paragraphs of Sandoz’s Counterclaims.

94. Paragraph 94 states legal conclusions to which no answer is required. To the extent an answer is required, Par does not dispute that a justiciable controversy exists between the parties regarding infringement of the ‘209 Patent. Except as expressly admitted, Par denies the remaining allegations of Paragraph 94.

95. Paragraph 95 states legal conclusions to which no answer is required. To the extent an answer is required, Par does not dispute that Sandoz seeks a declaration that the ‘209 Patent is not infringed by the Sandoz Proposed ANDA Products.

96. Par denies the allegations in Paragraph 96.

97. Par denies the allegations of Paragraph 97.

98. Par denies the allegations of Paragraph 98.

SIXTH COUNTERCLAIM
Invalidity of the ‘209 Patent

99. Par incorporates by reference its responses to each of the preceding paragraphs of Sandoz’s Counterclaims.

100. Paragraph 100 states legal conclusions to which no answer is required. To the extent an answer is required, Par does not dispute that a justiciable controversy exists between the parties regarding the validity of the ‘209 Patent. Except as expressly admitted, Par denies the remaining allegations of Paragraph 100.

101. Par denies the allegations in Paragraph 101.

102. Par denies the allegations of Paragraph 102.

103. Par denies the allegations of Paragraph 103.

104. Par denies the allegations of Paragraph 104.

105. Par denies the allegations of Paragraph 105.

SEVENTH COUNTERCLAIM
Noninfringement of the ‘239 Patent

106. Par incorporates by reference its responses to each of the preceding paragraphs of Sandoz’s Counterclaims.

107. Paragraph 107 states legal conclusions to which no answer is required. To the extent an answer is required, Par does not dispute that a justiciable controversy exists between the parties regarding infringement of the ‘239 Patent. Except as expressly admitted, Par denies the remaining allegations of Paragraph 107.

108. Paragraph 108 states legal conclusions to which no answer is required. To the extent an answer is required, Par does not dispute that Sandoz seeks a declaration that the ‘239 Patent is not infringed by the Sandoz Proposed ANDA Products.

109. Par denies the allegations in Paragraph 109.

110. Par denies the allegations of Paragraph 110.

111. Par denies the allegations of Paragraph 111.

EIGHTH COUNTERCLAIM
Invalidity of the ‘239 Patent

112. Par incorporates by reference its responses to each of the preceding paragraphs of Sandoz’s Counterclaims.

113. Paragraph 113 states legal conclusions to which no answer is required. To the extent an answer is required, Par does not dispute that a justiciable controversy exists between

the parties regarding the validity of the '239 Patent. Except as expressly admitted, Par denies the remaining allegations of Paragraph 113.

114. Par denies the allegations in Paragraph 114.

115. Par denies the allegations of Paragraph 115.

116. Par denies the allegations of Paragraph 116.

117. Par denies the allegations of Paragraph 117.

118. Par denies the allegations of Paragraph 118.

NINTH COUNTERCLAIM
Noninfringement of the '785 Patent

119. Par incorporates by reference its responses to each of the preceding paragraphs of Sandoz's Counterclaims.

120. Paragraph 120 states legal conclusions to which no answer is required. To the extent an answer is required, Par does not dispute that a justiciable controversy exists between the parties regarding infringement of the '785 Patent. Except as expressly admitted, Par denies the remaining allegations of Paragraph 120.

121. Paragraph 121 states legal conclusions to which no answer is required. To the extent an answer is required, Par does not dispute that Sandoz seeks a declaration that the '785 Patent is not infringed by the Sandoz Proposed ANDA Products.

122. Par denies the allegations in Paragraph 122.

123. Par denies the allegations of Paragraph 123.

124. Par denies the allegations of Paragraph 124.

TENTH COUNTERCLAIM
Invalidity of the ‘785 Patent

125. Par incorporates by reference its responses to each of the preceding paragraphs of Sandoz’s Counterclaims.

126. Paragraph 126 states legal conclusions to which no answer is required. To the extent an answer is required, Par does not dispute that a justiciable controversy exists between the parties regarding the validity of the ‘785 Patent. Except as expressly admitted, Par denies the remaining allegations of Paragraph 126.

127. Par denies the allegations in Paragraph 127.

128. Par denies the allegations of Paragraph 128.

129. Par denies the allegations of Paragraph 129.

130. Par denies the allegations of Paragraph 130.

131. Par denies the allegations of Paragraph 131.

ELEVENTH COUNTERCLAIM
Noninfringement of the ‘223 Patent

132. Par incorporates by reference its responses to each of the preceding paragraphs of Sandoz’s Counterclaims.

133. Paragraph 133 states legal conclusions to which no answer is required. To the extent an answer is required, Par does not dispute that a justiciable controversy exists between the parties regarding infringement of the ‘223 Patent. Except as expressly admitted, Par denies the remaining allegations of Paragraph 133.

134. Paragraph 134 states legal conclusions to which no answer is required. To the extent an answer is required, Par does not dispute that Sandoz seeks a declaration that the ‘223 Patent is not infringed by the Sandoz Proposed ANDA Products.

135. Par denies the allegations in Paragraph 135.

136. Par denies the allegations of Paragraph 136.

137. Par denies the allegations of Paragraph 137.

TWELFTH COUNTERCLAIM
Invalidity of the ‘223 Patent

138. Par incorporates by reference its responses to each of the preceding paragraphs of Sandoz’s Counterclaims.

139. Paragraph 139 states legal conclusions to which no answer is required. To the extent an answer is required, Par does not dispute that a justiciable controversy exists between the parties regarding the validity of the ‘223 Patent. Except as expressly admitted, Par denies the remaining allegations of Paragraph 139.

140. Par denies the allegations in Paragraph 140.

141. Par denies the allegations of Paragraph 141.

142. Par denies the allegations of Paragraph 142.

143. Par denies the allegations of Paragraph 143.

144. Par denies the allegations of Paragraph 144.

AFFIRMATIVE DEFENSES

First Affirmative Defense

Defendant’s Counterclaim fails to state a claim upon which relief can be granted.

PRAYER FOR RELIEF

Par denies all remaining allegations not expressly admitted or responded to herein. Par further denies that Sandoz is entitled to the relief requested, or to any relief whatsoever. Par prays for relief as follows:

- A. Entry of judgment in favor of Par and against Sandoz with respect to Defendant's Counterclaims, and an award of relief sought in Par's Complaint;
- B. Dismissal of Sandoz's Counterclaims with prejudice;
- C. An award to Par of its attorney's fees, costs, and expenses; and
- D. Such other relief as the Court deems equitable and just.

DATED: December 11, 2018

/s/ Robert D. Rhoad

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CERTIFICATE OF SERVICE

I hereby certify that on December 11, 2018, I caused a true and correct copy of the foregoing ANSWER TO DEFENDANT’S COUNTERCLAIMS to be served via the Court’s CM/ECF system and via email on the following counsel of record:

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